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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	ENDOV-48232
First Inventor or Application Identifier	Arnold Escano
Title	Reduced Profile Grafting System
Express Mail Label No.	EL457694535US

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APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)* *(Submit an original and a duplicate for fee processing)*
2. [X] Specification [*Total Pages* 54]
   (preferred arrangement set forth below)
   - 1 - Descriptive title of the Invention
   - - Cross References to Related Applications
   - - Statement Regarding Fed sponsored R & D
   - - Reference to Microfiche Appendix
   - 5 - Background of the Invention
   - 6 - Brief Summary of the Invention
   - 2 - Brief Description of the Drawings *(if filed)*
   - 26 - Detailed Description
   - 12 - Claim(s)
   - 1 - Abstract of the Disclosure
3. [17] Drawing(s) *(35 U.S.C. 113)* [*Total Sheets* 10]
4. Oath or Declaration [*Total Pages* 3]
   a. [X] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d)) *(for continuation/divisional with Box 16 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

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5. [ ] Microfiche Computer Program *(Appendix)*
6. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Copy
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   c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [X] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
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12. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
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APPLICATION

of

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and

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for

UNITED STATES LETTERS PATENT

on

REDUCED PROFILE GRAFTING SYSTEM

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REDUCED PROFILE GRAFTING SYSTEM

BACKGROUND OF THE INVENTION

This invention relates to a system and method for emplacing a prosthesis and more particularly, to a reduced profile delivery system and method of use for placement within a corporeal lumen of a novel bifurcated graft having attachment systems.

It is well established that various fluid conducting bodies or corporeal lumens, such as veins and arteries, may deteriorate or suffer trauma so that repair is necessary. For example, various types of aneurysms or other deteriorative diseases may affect the ability of the lumen to conduct fluids and in turn may be life-threatening. In some cases, the damaged lumen is repairable only with the use of a prosthesis such as an artificial vessel or graft.

For repair of vital vessels, such as the aorta, surgical repair is significantly life-threatening. Surgical techniques known in the art involve major surgery in which a graft resembling the natural vessel is spliced into the diseased or obstructed section of the natural vessel. Known procedures include surgically bypassing the damaged or diseased portion of the vessel and inserting an artificial or donor graft attached to the native vessel by an anastomosis.

It is known within the art to provide a prosthesis for intraluminal repair of a vessel, such as an abdominal aorta having an aneurysm. The art has taught to provide a prosthesis positioned in a vessel and then to secure the prosthesis within

the vessel with hooks or staples. Improvements since the earliest prosthesis and intraluminal delivery systems have attempted to increase the flexibility of the entire grafting system and reduce the complexity of the implantation procedure.

More recent art has taught the use of bifurcated grafts having attachment systems configured on each end of the graft prior to delivery. These attachment systems required the use of multiple balloon catheters to expand each of the attachment systems individually. Although these recent improvements simplify the procedure and reduce risks to the patient, more improvement is possible.

In recent years, several devices have been developed to attempt to treat an aortic aneurysm through intraluminal repair. For example, a method and article for performing an aneurysm repair, wherein a prosthetic graft is utilized to replace the damaged segment of the blood vessel have previously been developed. A plurality of radially spaced anchoring pins are located adjacent each end of the graft and provide means for securing the graft to the wall of the vessel. An assembly is provided for moving the graft within the vessel and permanently anchoring the graft to the wall of the vessel.

Additionally, there has been previously described a bifurcated aortic graft constructed for intraluminal insertion having a plurality of struts having angled hooks with barbs at their superior ends. An assembly for inserting the graft and implanting the hooks into the vessel lumen is also disclosed.

Others have disclosed an intraluminal grafting system including a hollow graft having an attachment means located at one end of the graft. The system

includes positioning means for moving the graft within the vessel, the positioning means having a capsule positioned at one end for covering the graft attachment means. The disclosed positioning means further includes an inflatable member for securing the attachment means within the lumen.

Moreover, there has been described an aortic graft and apparatus for repairing an aneurysm that includes a tube graft secured within the aorta and an attachment means at each end of the graft. Intraluminal delivery is accomplished using a catheter having a balloon for expanding and securing the attachment means. The graft and attachment means are preferably enclosed by a sheath which covers the entire graft and attachment means.

There have also previously been developed arrangements including an intraluminal grafting system including a tubular graft having attachment means positioned at both ends. The system includes a positioning means for transporting the graft through a vessel lumen and for deploying the graft within the lumen. The positioning means includes an inflatable member, a capsule and means for removing the graft from the capsule. The capsule is disclosed as a rigid cylindrical member covering the entire graft.

A sheath for use in introducing a catheter in the body of a patient has also been previously described. The sheath includes a flexible elongate tube and a backflow adapter having a hemostatic valve secured to the proximal extremity of the tube. The sheath may be used for introducing a deployment catheter into a femoral artery of the patient.

To provide consistency with the common usage of terms used in the medical surgical arts in the United States, the terms "proximal, distal, inferior and superior" are used with a certain regularity within the present specification. Proximal refers to parts of the system, such as catheters, capsules and wires, which are closest to the user and closest to that portion of the system lying outside or exterior of the patient. Distal refers to the point farthest from the user and typically most interior of the corporeal lumen. The term superior refers to a location situated upstream of the flow of blood and is used herein in description of the graft and attachment system. Inferior refers to the point situated downstream of the flow of blood and again is used herein with reference to the graft and attachment system.

A typical procedure used with the described invention uses a "femoral approach." This term describes an application which begins with an incision in the femoral artery. Similarly, the described invention may be used in an "iliac approach" which begins with an incision in the iliac artery. Using the terminology defined in the previous paragraph, the distal tip of the system may be inserted into the femoral artery and advanced upstream into the iliac artery and the abdominal aorta. Thus, the more distal portions of the system reside upstream of those portions described as more proximal. Furthermore, in the described procedure, the superior portions of the graft will permanently reside in the abdominal aorta, while the inferior portions will reside in the iliac arteries.

The terms "ipsilateral" and "contralateral" typically refer to opposing portions of a corporeal lumen having symmetric right and left sides. "Ipsilateral"

refers to those portions residing on the same side through which the grafting system enters the corporeal lumen, while "contralateral" refers to the opposite portions. Therefore, this distinction is dependent on whichever side (right or left) the physician decides to insert the grafting system. The portions of the grafting system which reside or operate within the symmetric vessels of the corporeal lumen use the same terminology. For example, the physician may insert the grafting device into the ipsilateral femoral artery, advance the device through the ipsilateral iliac artery and into the abdominal aorta. Then the device can be manipulated downstream into the contralateral iliac artery.

SUMMARY OF THE INVENTION

The present invention embodies an intraluminal delivery system for securing a prosthesis within the vessels of the corporeal lumen of an animal, such as a human. The preferred embodiment of a placement system is configured for introducing a graft into a corporeal lumen and positioning the graft in the area of the aortic bifurcation. The delivery system embodies a main catheter capable of containing the prosthesis and placement system for intraluminal delivery. A significant improvement of this system is the use of a main catheter having a smaller diameter from the prior art systems.

In general, it is an object of the present invention to provide an intraluminal grafting system and method which improves upon the prior art systems. One feature that impacts the capability of any intraluminal device or delivery system is the size of the system's components. Reducing the size of the components, and ultimately the total delivery system, allows accessing smaller arteries without injury as well as increasing flexibility. The challenges associated with reducing the size of the system have been met by the present invention. The mechanisms of the present invention have been arranged to fit within a smaller circumferential area than the prior art devices. Furthermore, the procedures associated with the present invention have been modified to reflect the novel arrangement of the mechanisms. This allows the use of a delivery catheter having diameter significantly smaller than what is taught in the prior art. The present invention comprises a system and method for implanting a prosthesis utilizing such a reduced diameter delivery catheter. The

reduced diameter delivery catheter is designed for traversing the femoral, iliac and aortic vessels of a human anatomy.

The present system has several advantages over prior art systems. For example, the reduced diameter delivery catheter causes less trauma to the femoral and iliac arteries while inserting and delivering the grafting system. In addition, the reduced diameter delivery catheter permits the use of the invention in a larger patient population because of the variances in iliac vessel diameters. Similarly, the smaller system diameter may allow for easier navigation inside the corporeal lumen especially with more difficult anatomy.

Additionally, the simplified delivery and attachment methods provide advantages to physician and patient which are not available with prior art devices. Ease of use eliminates many of the complications involved with other devices. Shorter procedure times allowed by simplified delivery further reduces the trauma to the patient due to interruption of the flow of blood through the aorta and iliac arteries.

The prosthesis delivered by the present system comprises an inverted wye-shaped bifurcated graft having an attachment system at each of its three orifices. The upper attachment system, which is used to anchor the graft into the abdominal aorta, preferably uses a series of sharpened outwardly disposed members to engage the aorta. The upper attachment system may be balloon-expandable, self-expandable or partially both. The two lower attachment systems, which are used to implant the graft into the iliac arteries, preferably employ self-expanding attachment

systems which also support the lower extremities of the graft, but may also be balloon expandable or partially both.

In the preferred embodiment, the two lower attachment systems, comprised of self- expanding attachment systems, are restrained in a compressed condition by release wires residing along side the elements of the attachment systems. These release wires are also described herein as "pull wires" which describes the method by which they release the attachment system. Once the graft is positioned correctly in the aorta and iliac arteries the release wires can be removed, allowing the attachment systems to expand. When the attachment systems are expanded the lower extremities of the graft are attached within the iliac arteries. The release wires can then be entirely removed from the patient leaving the graft securely attached within the iliac arteries.

Preferably, the self-expanding attachment systems in the lower extremities of the graft are arranged to extend superiorly near to the septum of the bifurcation and proximally below the orifice of each lower extremity. For example, the proximal end of the attachment systems may extend approximately 20mm below the proximal end of the lower extremity. The lower extremities are thus fully supported by the attachment systems when deployed which prevents twisting and bunching of the graft. The graft is also securely attached within the iliac arteries throughout the entire length of the attachment systems. This configuration allows for greater patient activity and mobility without dislodging the graft.

The upper, or superior, member of the graft is positioned by advancing the grafting system through the patient's vascular system. First the grafting system is inserted into the patient's ipsilateral femoral artery or external iliac artery. The grafting system is then advanced through the arteries until it passes through the ipsilateral iliac artery, past the aortic bifurcation and into the aorta. The system is then advanced through the aorta until it crosses the aneurysm to be treated. A portion of the main delivery catheter is then withdrawn relative to the remainder of the system exposing the graft. The superior member is thereby located within the aorta superior to the aneurysm.

As the main delivery catheter exposes the graft, the contralateral inferior member is exposed, as well as an attached contralateral delivery system. Preferably the contralateral delivery system includes a contralateral delivery catheter, a contralateral guidewire and a contralateral release wire fastened to the contralateral attachment system. The contralateral guidewire may include a knob or hook on its distal end. This knob or hook is configured to allow the contralateral guidewire to be snared by a wire designed for this purpose which is advanced through the contralateral femoral artery and iliac artery. Once the guidewire is snared the contralateral portion of the grafting system may be guided down into the contralateral iliac artery, and correctly positioned therein.

As the main delivery catheter exposes the graft, the proximal end of the ipsilateral inferior member remains attached within an ipsilateral delivery catheter. This ipsilateral delivery catheter is disposed throughout the main catheter and can be

independently translated. It is used to pull the ipsilateral inferior member back into the ipsilateral iliac artery, and correctly position it therein.

Preferably, the delivery system includes a balloon catheter assembly capable of expanding the attachment system of the superior member of the graft. Expanding the system in this manner urges the outwardly disposed members, if present, into the wall of the aorta which is one method of securely fastening the system thereto. Preferably, the balloon catheter has a multilumen catheter shaft. At least one of these lumens allows the inflation of the balloon. Others house the delivery system for the ipsilateral extremity, the release wire for the ipsilateral self-expanding attachment system, and the main guidewire. Preferably, the release wire is also housed within a small diameter cylinder which allows the balloon catheter to be advanced and retracted relative to the release wire.

The main guidewire extends distally beyond the remainder of the system. The main guidewire also extends proximally throughout the system and out of a control device such that its proximal end can be manipulated by the physician. In this manner the main guidewire may be advanced to a desired location and aid in the manipulation of the remainder of the system. Such a guidewire may be of a configuration typical to prior art procedures, or may be specifically designed for use in a reduced diameter delivery system.

The ipsilateral lower extremity of the graft is deployed the ipsilateral iliac artery by retracting the ipsilateral release wire. The physician has independent control of the ipsilateral release wire which may be pulled proximally with respect

to the remainder of the system. By pulling the ipsilateral release wire proximally it is unfastened from the members of the ipsilateral attachment system and the ipsilateral lower extremity. This allows the ipsilateral attachment system to expand toward the wall of the artery. The ipsilateral release wire and cylinder may then be removed from the patient and the system. Once the contralateral lower extremity is correctly positioned into the contralateral iliac artery, it may be deployed in much the same way as the ipsilateral lower extremity. The contralateral positioning system has various possible configurations. All of the configurations allow for the contralateral release wire to be pulled proximally with respect to the remainder of the system and unfastened from the contralateral extremity and contralateral attachment system. Once the contralateral release wire is withdrawn and the contralateral attachment system deployed, the remainder of the contralateral system may be removed from the patient and the system.

The remaining components of the system may be withdrawn from the patient at any time the components are free from the others. This leaves the graft in place and secured across the aortic bifurcation. The bifurcated graft safely maintains the blood flow throughout the region. Once the delivery system components are removed from the body, the access to the corporeal lumens may be closed.

Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a plan view of a bifurcated graft implanted in the aortic bifurcation of a human;

FIG. 2 is an enlarged partial cross-sectional plan view of the distal end of the delivery system configured for intraluminal delivery;

FIG. 3 is a plan view of the delivery system;

FIG. 4 is an enlarged partial cross-sectional plan view of a first embodiment of the grafting system with the bifurcated graft partially deployed;

FIG. 5 is an enlarged partial cross-sectional plan view of a second embodiment of the grafting system with the bifurcated graft partially deployed;

FIG. 6 is an enlarged partial cross-sectional plan view of a third embodiment of the grafting system with the bifurcated graft partially deployed;

FIG. 7 is an enlarged partial cross-sectional plan view of one embodiment of the components of the grafting system used to deploy the contralateral tubular leg;

FIG. 8 is a perspective view of the bifurcated graft with the attachment systems deployed;

FIG. 9A is a perspective view of a first embodiment of the superior end of the bifurcated graft as it would appear if unrolled;

FIG. 9B is a perspective view of a second embodiment of the superior end of the bifurcated graft as it would appear if unrolled;

FIG. 10 is an enlarged plan view of the apices and wall-engaging member a first embodiment of the superior attachment system of the bifurcated graft;

FIG. 11 is an enlarged plan view of the apices of another embodiment of the superior attachment system of the bifurcated graft;

FIG. 12 is a plan view of the control assembly of the delivery system;

FIG. 13 is a plan view of a delivery system being inserted into the abdominal aorta from the ipsilateral iliac artery;

FIG. 14 is a plan view of a partially deployed bifurcated graft being snared at the contralateral leg by a snare loop inserted through the contralateral iliac artery;

FIG. 15 is a plan view of a partially deployed bifurcated graft being pulled into position in both the ipsilateral and contralateral iliac arteries;

FIG. 16 is a plan view of a partially deployed bifurcated graft being implanted in the abdominal aorta; and

FIG. 17 is a plan view of a fully deployed bifurcated graft.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings and for purposes of illustration the invention is embodied in an intraluminal delivery system 20 for a bifurcated graft 24. The major components of the system include the bifurcated graft, a main catheter assembly 22, a balloon catheter assembly 26, and a control assembly 54. The delivery system 20 includes several components particular to the placement of the graft across a vascular bifurcation such as the aortic bifurcation. One of the novel features of the invention is the use of a main delivery catheter 23 having a diameter smaller than what has been achieved in prior art systems. Most of the components for the delivery and placement of the graft are delivered together within this reduced-diameter delivery catheter. Therefore, the system includes various novel features which allow it to be delivered within the reduced diameter of the delivery catheter. These features include providing simplified delivery mechanisms for both the ipsilateral and contralateral inferior legs of the prosthesis. Further features include simplified mechanisms for attaching the graft limbs and increased flexibility of the entire system.

In the present system, the graft 24 is comprised of a bifurcated tubular prosthesis having superior and inferior extremities. The superior member 34 of the graft comprises a main tubular member which bifurcates into two tubular legs 32 and 46 which comprise the inferior extremities of the graft. For clarity, the two tubular legs are referred to as the ipsilateral inferior member 32 and the contralateral

inferior member 46. An attachment system 60 is secured to the superior end of the main tubular member 34 as well as to the inferior ends of each of the tubular legs 32 and 46. The superior attachment system 60 secured to the superior member may be provided with wall-engaging members 74 which are retracted during delivery. A balloon catheter assembly 26 is included for expansion of the superior attachment system. The superior attachment system may also be self-expanding. The attachment system 78 and 80 of each inferior tubular member includes a self-expanding attachment system which is compressed during delivery. Release wires 112, 136 keep the attachment systems in a compressed condition until the bifurcated graft 24 is appropriately positioned. The attachment systems are expanded by pulling the release wires out of the attachment systems. Due to the integrated nature of the inferior members and these attachment systems, the references herein to the inferior tubular members may include the attachment systems, or where appropriate, the attachment system may be referenced separately.

Much of the terminology used herein is variable. Those skilled in the art will recognize many of the components described herein by other terms. For example, the parts of the bifurcated graft may be referred to as superior and inferior members as well as upstream and downstream ducts or as distal and proximal extremities. The attachment systems are also referred to as expandable anchors which is descriptive of how the systems operate. The delivery components include tubular devices known as catheters in many different configurations. There exists a main delivery catheter for delivery of the entire system as well as secondary catheters

which are used within the ipsilateral and contralateral blood vessels. The use of particular terminology herein is not intended as a limitation, rather terminology is intended to encompass the varied references known to those of skill in the art.

In more detail, the intraluminal grafting system 20 is shown in FIGS. 2-7. As shown in FIG. 2 the system includes a main catheter assembly 22, a bifurcated graft 24, and a balloon catheter assembly 26. The balloon catheter assembly is comprised of a balloon catheter shaft 28, and an expandable balloon member 30. The balloon catheter shaft 28 is disposed within the main delivery catheter 23 with the expandable balloon member 30 extending distally. The bifurcated graft is also shown collapsed within the delivery catheter.

The ipsilateral inferior member 32 and superior member 34 of the bifurcated graft 24 are disposed about the balloon catheter shaft 28. An ipsilateral delivery catheter 36 may also be disposed about the balloon catheter shaft 28 and at least the proximal end of the ipsilateral inferior member. A first cylinder 38 is also included within a first balloon catheter lumen 40. By way of example, the cylinder may be a hypotube. A main guidewire 42 may also be disposed within a second balloon catheter lumen (not shown).

Several different embodiments of the present invention are described herein. FIGS. 4, 5 and 6 each depict one possible embodiment of this invention. The differences between these embodiments are primarily within the components for the positioning of the contralateral inferior member 46. Although a contralateral

delivery catheter 130 is present in each embodiment, it has several possible configurations.

The contralateral inferior member 46 of the graft is disposed about a contralateral guidewire 48. The contralateral guidewire 48 may be formed as a stiffened wire or as a coiled wire. The proximal end of the contralateral inferior member 46 is attached to a contralateral delivery catheter 130. The contralateral guidewire 48 extends proximally through a first contralateral lumen 52. The contralateral delivery catheter 130 may include a substantial bend 131 (FIG. 2) so that the assembly may fit within the main delivery catheter 22. This bend 131 may occur midway through the length of the contralateral delivery catheter 130 and be comprised of any one of several types of flexible joints known in the art.

Those skilled in the art will appreciate that many of these components, which herein are described as parts of a graft delivery system, are also parts of related systems. For instance, the balloon catheter assembly 26, is part of a system which provides for the inflation, deflation, advancement and retraction of the balloon catheter 28. This balloon catheter system includes components on a control assembly 54 (Fig. 3) which is manipulated by the physician and remains outside of the patients vasculature. Similarly, the main guidewire 42 described as part of this invention is also part of a system designed for control of the guidewire. It should be appreciated that the details of these related systems may vary, or in fact be improved over time, without removing a device from the scope of this invention.

As shown in FIGS. 1 and 8-11 the intraluminal grafting system 20 also includes an expandable, collapsible and flexible intraluminal vascular bifurcated prosthesis or bifurcated graft 24 for implanting in a body vessel or corporeal lumen 56. Referring to FIG. 8, the graft consists of a deformable main tubular member 34 which bifurcates into an ipsilateral tubular member 32 and a contralateral tubular member 46. The main tubular member 34 and inferior tubular members 32, 46 each are formed of a graft wall 58 allowing fluid communication between the superior and inferior ends of the bifurcated graft 24.

The main tubular member 34 may have a length in the range of two to ten centimeters, where 7.5 centimeters is suitable for most patients. The main tubular member 34 may have a maximum expandable diameter ranging from fourteen to forty millimeters and a minimum diameter in a collapsed condition of less than .3 inches (7.66mm). The ipsilateral inferior member 32 and the contralateral inferior member 46 may have lengths in the range of three to ten centimeters, where five centimeters is suitable for most patients. The graft wall 58 may be manufactured of any surgical implantable material such as a polytetrafluoroethylene or a polyester fiber made from polyethyleneterephthalate (PET) such as DACRON (Type 56). One fluid-tight woven material found to be satisfactory is ENDOWEAVE™ 45. In order to prevent unraveling of the woven material at the ends, the ends may be melted with heat to provide a fusion bead of material on each end.

Referring to FIGS. 8-11, an expandable superior attachment system 60 is secured adjacent the distal end of the main tubular member 34. The superior

attachment system may be formed of a plurality of apices 62 with the outer apices 64 and inner apices 66 of the superior attachment system 60 possibly being formed with helical torsion springs 68. The superior attachment system 60 may be comprised of apices 62 numbering from four to twenty-four. The springs yieldably urge the legs 70 and 72 attached to each of the apices outward. The superior attachment system 60 has both long legs 70 and short legs 72 which stagger the apices 62 along the superior end of the graft 24.

Preferably, the superior attachment system 60 is comprised of a single piece of wire which is formed to provide the apices 62 and also to define helical torsion springs 68 between legs 70 and 72. In a preferred embodiment, the turns of the apexes defined by the wire having an inner diameter equal to .032 inches. The ends of the single piece of wire may be welded together to form a continuous spring like attachment system.

As shown in FIG. 9A, wall-engaging members 74 are preferably secured to the legs 70 and 72 of the superior attachment system 60 in the vicinity of the outer apices 64 by suitable means such as a weld 76. Another embodiment, shown in FIG. 9B, uses wall-engaging members 74 in a vee configuration with the wall-engaging members 74 being on the ends of legs extending from the apex. The wall-engaging members 74 have a cross-sectional diameter ranging from .007 to .018 inches (.254 to .457mm) and a length from .5 to 5.0 millimeters. The wall-engaging members 74 are bent as hooks and preferably the apex has an inner diameter equal to .032 inches. The wall-engaging members 74 are preferably sharpened to provide

conical tips, and should have a length which is sufficient for the tip to penetrate into and perhaps through the corporeal lumen wall.

The superior attachment system 60 and wall-engaging members 74 may be formed from any suitable, corrosion resistant wire material. One such material is ELGILOY™ which is a cobalt-chromium-nickel alloy manufactured and sold by Elgiloy of Elgin, Illinois. The wire may have a diameter ranging from .008 to .016 inches (.203 to .406 mm).

As shown in FIG. 8, the ipsilateral attachment system 78 and the contralateral attachment system 80 are provided on the ipsilateral inferior member 32 and contralateral inferior member 46 respectively. These attachment systems may be provided as self-expanding vascular endoprosthesis. One such endoprosthesis is constructed similar to the braid design of the SCHNEIDER WALLSTENT® produced by Schneider, Inc. of Minneapolis, Minnesota, and described as a tracheobronchial endoprosthesis. A 14 mm stent diameter by 90 mm stent length is particularly suited to this application. The endoprosthesis may have a woven or braided structure which expands independently after being compressed for delivery. Such self-expanding endoprosthesis operate as coiled springs which, when released inside a vessel, independently expand to the wall of the vessel. When expanded these endoprosthesis anchor the inferior legs of the graft into the corporeal lumen as well as preventing kinking of the inferior members.

Preferably the ipsilateral attachment system 78 and the contralateral attachment system 80 are disposed within the ipsilateral inferior member 32 and the

contralateral inferior member 46 respectively. The attachment systems should be arranged such that upon implantation the superior end of the ipsilateral attachment system 78 and the superior end of the contralateral attachment system 80 are located proximate the septum 82 of the bifurcated graft 24. Preferably, this will result in the inferior end of the attachment systems extending about 20 mm proximal to the inferior end of the ipsilateral tubular member 32, and the inferior end of the contralateral tubular member 46. As the braided type of endoprosthesis contracts in length while expanding in diameter, the preferred arrangement upon implantation is positioned appropriately before full deployment. A simple calculation of the amount of contraction due to the desired expansion will allow the endoprosthesis to be appropriately placed during the manufacture of the prosthesis to allow for the proper positioning upon expansion. The preferred embodiment is to use an endoprosthesis which has a maximum diameter larger than the maximum diameter of the tubular member, such as using the 14 mm diameter (relaxed state) endoprosthesis previously described with a 13 mm diameter maximum tubular member.

The superior attachment system 60, the ipsilateral attachment system 78, and the contralateral attachment system 80, are attached to the graft wall 58 of the bifurcated graft 24 by suitable means such as a polyester suture material. As shown in FIGS. 9A and 9B sutures 84 are used for suturing the inner apices 66 of the superior attachment system onto the graft wall of the superior member 34. Additional sutures 86 are preferably formed on each of the long legs 70 and the

short legs 72 of the superior attachment system to firmly secure each leg to the graft. The inferior attachment systems may be secured to the each inferior member by sutures near the superior end of the attachment system. The sutures are arranged such that the attachment systems and inferior members are attached while both are compressed and while both are expanded.

As shown in FIG. 12, the control assembly 54 of this invention is composed of a handle 88, a plurality of ports 90, 96, 114 and control devices 92, 94, 104, 108, 110. Preferably the control assembly 54 of this invention will generally conform to the control assembly of the grafting system sold under the trade name ANCURE™ by Endovascular Technologies, Inc., Menlo Park, California. The handle 88 is configured such that a physician can grip the system and manually advance or retract the entire system. The plurality of ports 90, 96, 114 are provided to allow the introduction of fluids and guide wires into the system. The plurality of control devices 92, 94, 104, 108, 110 are provided to facilitate the manipulation of the system's various components by the physician.

The guidewire port 90 allows the introduction, advancement and retraction of guidewires (not shown) independent of the remainder of the system. A variety of guidewires may be used with this system. Guidewires may be entirely withdrawn from the system via the guidewire port and a new guidewire inserted while the grafting system 20 remains in the patient's vasculature. Preferably, the guidewire accesses a lumen in the balloon catheter assembly 26 specifically adapted for the advancement and retraction of the guidewire.

The balloon catheter assembly 26 is controlled by several components on the control assembly 54. A balloon lock 92 maintains the position of the balloon catheter locked in relationship to the remainder of the grafting system while it is in the lowered position. Once the balloon lock 92 is lifted, a balloon grip 94 may be used to retract and advance the balloon catheter shaft 28 and expandable balloon member 30 relative to the remainder of grafting system. Once the expandable balloon member 30 is retracted into the desired position, the balloon may be expanded via a balloon inflation port 96. The balloon inflation port 96 accesses a lumen within the balloon catheter which is in fluid communication with the expandable balloon member 30. The physician inflates the balloon by introducing a pressurized fluid into the inflation port.

A main catheter lock 98 is located on the main delivery catheter 23 distal to the remainder of the control assembly 54. The main catheter lock 98 prevents the relative motion of the main catheter assembly 22 to the remainder of the system while a tightening portion 100 is bound to a fixed portion 102 of the main catheter lock 98. To unbind the two portions of the lock 98, the physician unscrews the tightening portion 100 to loosen the main catheter lock 98 from the main delivery catheter 23. By gripping and pulling the main catheter lock 98 proximally, the main delivery catheter assembly 22 can be translated proximally with respect to the remainder of the grafting system 20. This process exposes the main tubular member 34, the contralateral inferior member 46 and the contralateral positioning components.

A superior pull ring 104 (Fig. 3) is attached to a superior release wire 106 (See Fig. 2) in those configurations which utilize such a wire. Pulling the superior pull ring 104 will withdraw the superior release wire 106 and unbind the superior attachment system 60.

A slide grip 108 is positioned on the handle 88 and connected to the ipsilateral delivery catheter 36. By pulling the slide grip 108 proximally, the ipsilateral delivery catheter 36 is translated proximally with respect to the remainder of the grafting system. This pulls the ipsilateral inferior member 32 of the bifurcated graft 24 into the ipsilateral iliac artery and exposes the ipsilateral attachment system 78.

An ipsilateral pull ring 110 (Fig. 12) is attached to the ipsilateral release wire 112 (See Fig. 4). Pulling the ipsilateral pull ring will 110 withdraw the ipsilateral release wire 112 and unbind the ipsilateral attachment system 78.

A flush port 114 is also located on the control assembly 54. This port can be used to flush the grafting system with fluid, preferably heparinized saline. This prevents trapped air from entering the patient's vasculature due to manipulation of the grafting system 20.

Preferably, the components of the control assembly 54 sequentially interrelate such that the components can only be deployed in a certain order. For example, the slide grip 108 may be locked into the distal position until the superior pull ring 104 is withdrawn. This prevents the physician from exposing the

ipsilateral attachment system 78 prior to deploying the superior attachment system 60. Such features enhance the safety of the grafting system.

The sizing of the bifurcated graft 24 may be performed on a patient by patient basis, or a series of sizes may be manufactured to adapt to most patient's needs. For the repair of an aortic aneurysm, the length of the bifurcated graft is selected so as to span at least one centimeter superior and one centimeter inferior of the aneurysm, whereby the attachment systems and graft can contact healthy tissue of the vessel on both sides of the aneurysm. Thus, the bifurcated graft, not including the attachment systems, should be at least two centimeters longer than the aneurysm being repaired. During the pre-implant fluoroscopy procedure, a conventional pig tail angiography catheter is used to determine the locations of the renal arteries to ensure the renal arteries will not be covered by the implanted graft. Likewise, on the inferior end of the corporeal lumen, determining the location of the internal iliac arteries ensures that they will not be covered by the solid portion of the implanted graft. Also, the diameter of the main tubular member 34 is selected by measuring the corporeal lumen which will receive the graft by conventional radiographic techniques and then selecting a graft with a main tubular member having a diameter the same as measured and preferably at least one millimeter larger than that measured.

The bifurcated graft 24 preferably contains a plurality of radiopaque markers 116 for locating the graft and for detecting any twisting of the graft during deployment. FIG. 8 shows one possible arrangement of radiopaque markers 116.

Such an arrangement of radiopaque markers will assist in the proper delivery and placement of the graft.

Another feature of this invention is the main catheter assembly 22. This assembly includes a main delivery catheter 23, a catheter ring 120 (Fig. 2) and components of the control assembly. The catheter ring 120 is a metallic cylinder, preferably composed of a 300 series stainless steel, proximate the distal end of the main delivery catheter 23. The main delivery catheter 23 forms the primary delivery vessel or container of the grafting system 20 in that the majority of the components of the graft 24 are located within the main delivery catheter 23 while being delivered to the aorta. The main catheter assembly 22 provides protection for both the grafting system components and the blood vessels. One novel feature of the main delivery catheter 23 and catheter ring 120 used in this invention is the reduced diameter of the main catheter assembly 22 capable of delivering a complete bifurcated grafting system. The simplified delivery systems and attachment systems are notable features which allow this reduced diameter. The use of a main catheter assembly 22 measuring 20.7 French in diameter has been demonstrated effectively. Several delivery systems conforming to this specification were built each having a main catheter assembly 22 with a 20.7 French diameter. The innovations of this invention permit the use of a catheter assembly approximately as small as 20 French in diameter to deliver a complete aortic bifurcation grafting system. This reduced diameter for delivery of a bifurcated graft greatly eases the procedure of implanting

the graft. A smaller diameter delivery device reduces the stress to the patient's system, easing healing and recovery.

The French scale is used in the medical field to measure the diameter of blood vessels and medical equipment for delivery into blood vessels. One French equals one-third of a millimeter or approximately .013 inches. (3F = 1 mm). Therefore, 20.7 French = 6.9 mm or approximately .272 inches in diameter.

The intraluminal grafting system 20 is delivered via this reduced diameter main catheter assembly 22. Although portions of the balloon catheter assembly 26 and main guidewire 42 extend distally from the distal end of the main catheter assembly, the bulk of those components reside therein during delivery. Generally, the components residing within the main catheter assembly include the bifurcated graft 24, the components for delivering the superior tubular member to the aorta, the components for delivering the ipsilateral inferior tubular member to the ipsilateral iliac artery and those components for delivering the contralateral inferior member to the contralateral iliac artery.

In preferred embodiments, and as shown in FIGS. 4 and 5, the components used for delivering the ipsilateral inferior member 32 to the ipsilateral iliac artery include the ipsilateral delivery catheter 36, a first cylinder 38, an ipsilateral release wire 112, and an ipsilateral end cap 122. Whether the ipsilateral iliac artery refers to the right or left iliac artery depends upon the choice of the physician in inserting the system into either artery.

The ipsilateral delivery catheter 36 may be a polyimide catheter shaft, or any other suitable elongated member. It may also be comprised of a series of tubular members. The distal end of the ipsilateral delivery catheter 36 may be disposed about the proximal end of the compressed ipsilateral attachment system 78. Furthermore, the ipsilateral delivery catheter 36 is disposed about the balloon catheter shaft 28. The ipsilateral delivery catheter 36 is contained by the main delivery catheter 23. Various size catheters may be used for the ipsilateral delivery catheter dependent upon the reduced diameter of the main catheter assembly 22. One size which is particularly suited to these requirements is a .125 inch inner diameter catheter.

The first cylinder 38 (Figs. 2, 4, 5, 6) may be disposed entirely within a lumen of the balloon catheter assembly 26. The interface between the first cylinder 38 and the balloon catheter shaft 28 permits relative motion such that the balloon catheter assembly 26 may be advanced and retracted without moving the first cylinder 38. The first cylinder 38 contains the ipsilateral release wire 112. This interface also permits relative motion so that the ipsilateral release wire 112 may be pulled through the first cylinder 38. Near its distal end the first cylinder 38 has a plurality of portals 124 which access an inner lumen 126 of the cylinder 38. These portals 124 permit the ipsilateral release wire 112 to be threaded between the first cylinder 38, the ipsilateral attachment system 78 and the ipsilateral inferior member 32. To facilitate this connection the balloon catheter shaft 28 has at least one cutaway 128 which allows the ipsilateral release wire to pass between the cylinder

(on the interior of the balloon catheter shaft) and the bifurcated graft (on the exterior balloon catheter shaft). The cutaway 128 may be elongated so that relative motion between the cylinder and the balloon catheter assembly is not hindered by the ipsilateral release wire 112. The first cylinder 38 may consist of a relatively rigid thin-walled tube formed of a suitable biocompatible material such as stainless steel. The first cylinder 38 must have an inner lumen sufficiently large enough to contain the ipsilateral release wire 112.

The ipsilateral release wire 112 may be formed from Nitinol. The purpose of the ipsilateral release wire is to keep the ipsilateral attachment system 78 from deploying until the bifurcated graft 24 is properly positioned with the ipsilateral inferior member 32 located within the ipsilateral iliac artery. The ipsilateral release wire 112 may be releasably attached over or around the self-expanding ipsilateral attachment system 78 and the ipsilateral inferior member 32 to prevent the ipsilateral attachment system 78 from expanding. As the ipsilateral release wire 112 is pulled proximally, it is detached from the attachment system 78 and releases the self-expanding attachment system 78 which expands the ipsilateral inferior member and secures it to the wall of the iliac artery.

As shown in FIG. 5, the preferred embodiment includes an ipsilateral end cap 122. The purpose of the ipsilateral end cap is to protect the distal end of the ipsilateral attachment system 78. The ipsilateral end cap may be comprised of shrink tubing or be formed from a hypotube and a suitable washer shaped member. In the preferred embodiment, the ipsilateral end cap is slidably secured to the

balloon catheter shaft 28, so that it remains over the distal end of the ipsilateral attachment system while the balloon catheter assembly is extended and retracted. The ipsilateral attachment system exerts sufficient expansile force to slide out of the ipsilateral end cap during deployment.

In the preferred embodiment, and as shown in FIGS. 4-7 the components used for delivering the contralateral inferior member 46 to the contralateral iliac artery may include a contralateral delivery catheter 130, a second cylinder 132, a contralateral guidewire 48, a contralateral release wire 136, a contralateral release wire pull handle 150, and a contralateral end cap 140. Whether the contralateral iliac artery refers to the right or left iliac artery depends upon the choice of the physician in inserting the system into either artery.

The contralateral delivery catheter 130 may be composed of multiple segments. Preferably, the most distal segment is a contralateral end cap 140 which extends over the proximal end of the compressed contralateral attachment system 80. The capsule contralateral end cap 40 is further attached to the distal end of an elongated hollow member 144. This elongated hollow member 144 may be comprised of a Hytrel bilumen catheter as shown in FIG. 4. Alternatively, the elongated hollow member 144 may be a coiled wire segment or a series of coiled wire segments and hypotubes as shown in FIG. 5. Another possibility is the use of HDPE tubing to form the elongated tubular member as shown in FIG. 6.

As shown in FIGS. 4, 5, and 6 the contralateral delivery catheter 130 either houses, or integrally forms a contralateral guidewire 48. The contralateral

guidewire may be formed as a stiffened wire as shown in FIG. 4, or as a coiled guidewire as shown in FIG. 5. Preferably, the contralateral guidewire has a hook 146 or a bulbous portion 147 (Fig. 2) formed on the proximal end. This hook 146 or bulbous portion 147 facilitates the snaring of the contralateral guidewire and contralateral delivery catheter by an appropriate device inserted from the contralateral iliac artery. This device may then be used to withdraw the proximal end of the contralateral guidewire through the contralateral femoral artery. This allows the manipulation of the contralateral guidewire and contralateral delivery catheter by the physician. By use of the contralateral guidewire and jacket, the contralateral inferior member 46 may then be pulled into the contralateral iliac artery.

As shown in FIGS. 4-6, the contralateral delivery catheter 130 also houses the contralateral release wire 136. Preferably, the distal end of the contralateral release wire is threaded between the distal portion of the assembly 130, the compressed contralateral attachment system 80, and the contralateral tubular member 46. The contralateral release wire therefore maintains the contralateral attachment system in the compressed state and maintains the relative position between the contralateral jacket and contralateral inferior tubular member. Furthermore, the contralateral release wire is fastened near the proximal end of the contralateral delivery catheter by side portals 148 in the contralateral delivery catheter and the contralateral release wire. This arrangement may prevent the relative motion of the release wire from the contralateral guidewire and jacket.

As shown in FIGS. 4-7 the proximal end of the contralateral release wire 136 may have a pull handle 150. Preferably, this pull handle is formed from stainless steel and is disposed about the guidewire. The contralateral release wire may be connected to the pull handle by a knot in the release wire disposed in a narrowing lumen 152 (Fig. 7) in the pull handle.

The pull handle 150 and the contralateral release wire 136 may be withdrawn proximally relative to the contralateral delivery catheter 130 to release the attachment formed by the release wire in the compressed contralateral attachment system 80, the elongated hollow member 144 and the contralateral inferior member 46 of the bifurcated graft 24. The contralateral attachment system may then expand the contralateral inferior member and secure the bifurcated graft to the contralateral iliac artery. Furthermore, the contralateral delivery catheter is released from the contralateral inferior member allowing the components of the contralateral delivery catheter to be withdrawn through the contralateral iliac artery and removed from the patient's vasculature.

As shown in FIGS. 4-6, a contralateral end cap 140 may also be connected to one of the components for delivering the contralateral inferior member 46. The contralateral end cap may be attached to the contralateral guidewire 48 as shown in FIG. 4 or to the second cylinder 132 as shown in FIGS. 5, 6. The contralateral end cap protects the contralateral attachment system 80 during delivery of the bifurcated graft 24 and the contralateral inferior tubular member. If the contralateral end cap is formed as an end cap as shown in FIGS. 5-6, the contralateral attachment system

may be expanded with the contralateral end cap in place. The contralateral end cap may also be formed as a capsule as shown in FIG. 4. This configuration would limit the expansion of the contralateral attachment system, requiring that the contralateral end cap be translated distally prior to contralateral attachment system expansion. Therefore, in this configuration the contralateral guidewire 48 is formed as a stiffened wire. This stiffened wire is slidably disposed within the contralateral delivery catheter allowing the contralateral guidewire and contralateral end cap to be advanced distally.

By way of example, FIGS. 13-17 depict a method for repair of an aortic aneurysm using the present invention for intraluminal placement of a graft in an aorta. First, a patient is prepared in a conventional manner by use of a guidewire, a dialator and sheath to access both ipsilateral and contralateral femoral arteries or iliac arteries of the patient. The distal end of the intraluminal grafting system 20 is then inserted into the sheath (not shown), which has previously been placed in the ipsilateral femoral artery. In the preferred embodiment of the present invention, the balloon catheter assembly 26 defines a lumen for receiving the guidewire that is traversed across the aneurysm. The following procedure may also be used when the guiding member is constructed as part of the balloon catheter.

Next, the balloon catheter assembly 26, the main guidewire 42, and the main catheter assembly 22 containing the remainder of the delivery system are all configured for deployment. As shown in FIG. 13 the assemblies may be advanced by the physician as a single unit over the main guide wire 42. The main guidewire

is introduced by the physician into a cutdown in the corporeal lumen and advanced through the ipsilateral iliac artery 200 to the desired location in the abdominal aorta 202 and adjacent to the diseased or damaged portion of the vessel.

The physician advances the distal end of the intraluminal grafting system 20 through the ipsilateral femoral artery over the main guidewire 42 while maintaining slight tension on the guiding tube assembly (not shown). Typically, the desired position for implanting the bifurcated graft 24 will be within the abdominal aorta 202 with the superior extremity of the main tubular member 34 inferior to the lower renal artery. The inferior attachment systems 78, 80 may be positioned over or approximately .5 centimeters superior to the internal iliac arteries. Fluoroscopy is used to inspect the position of the radiopaque section of the main catheter assembly 22 to ensure that the system is not twisted.

When the intraluminal grafting system 20 is in the desired position as shown in FIG. 13 the tightening portion 100 of the main catheter lock 98 is loosened to allow relative motion of the main delivery catheter 23. While using one hand to firmly grasp the control assembly the physician uses the other hand to gently pull the main catheter assembly proximally. This will withdraw the main delivery catheter proximally with respect to the remainder of the grafting system. The distal end of the superior member 34 and the contralateral inferior member 46 of the bifurcated graft will become exposed.

In some configurations the superior attachment system 60 will be prevented from expanding during delivery by a superior release wire 106. This release wire is

fastened around the superior extremity of the bifurcated graft 22 and the superior attachment system preventing expansion of both (not shown). The superior release wire also extends proximally throughout the grafting system to the control assembly 54. Once the superior attachment system is exposed from the main catheter it may be deployed and secured into the abdominal aorta 202. This may be done before or after the remainder of the bifurcated graft and attachment systems are exposed from the main delivery catheter 23. The superior release wire attached to the superior attachment system is withdrawn by pulling the superior pull ring 104. Once the superior release wire is removed the superior attachment system expands due to the spring force of the system.

Once the superior attachment system 60 has been expanded, the expandable balloon member 30 can be positioned to force the attachment system and the outwardly disposed wall-engaging members 74, if present, into the wall of the abdominal aorta 202. In the preferred embodiment, the balloon member can be retracted into position by lifting the balloon lock lever 92, and then pulling proximally on the balloon grip 94. Once the balloon is in position inside the superior extremity of the bifurcated graft and the balloon lock has been secured, the balloon member may be inflated. Inflation of the balloon member is accomplished by forcing a fluid (inflation media) into the balloon inflation port 96. A typical balloon can be inflated by a pressure up to 30psi. Inflation for one minute, and repeating at least once more is typically sufficient to secure the superior extremity and superior attachment system into the wall of the aorta.

Once the superior attachment system 60 has been positioned in the abdominal aorta 202, the remainder of the bifurcated graft 24 and delivery system may be exposed. To expose these components the main delivery catheter 22 is further translated proximally. When first exposed, both the contralateral inferior member 46 and the ipsilateral inferior member 32 will be located within the abdominal aneurysm 203, as shown in FIG. 14. The ipsilateral delivery catheter 36 will still be attached to the ipsilateral inferior member. The contralateral delivery catheter 50 will still be attached to the contralateral inferior member.

After being exposed the contralateral inferior member 46 may be positioned into the contralateral iliac artery 204. A snare loop 154 or similar device is advanced percutaneously or into the cutdown in the contralateral femoral artery. The snare loop is advanced through the contralateral femoral artery and iliac artery. The exposed contralateral guidewire 48 may then be captured ("snared") by the snare loop, preferably at the hook 146 or knob formed in the end of the contralateral guidewire 48. By withdrawing the snare loop and contralateral guidewire 48, the contralateral jacket assembly 130 and the contralateral inferior member can be manipulated via the contralateral guidewire.

The contralateral inferior member 46 may then be pulled out of the abdominal aorta proximally into the contralateral iliac artery by pulling the contralateral guidewire 48. Once the contralateral inferior member and contralateral attachment system 80 are positioned as desired, the attachment system may be deployed.

In the preferred embodiment, the contralateral release wire 136 is disposed throughout the contralateral delivery catheter 130 such that the contralateral release wire may be accessed by the physician once the contralateral delivery catheter extends proximally out of the femoral artery. Furthermore, the contralateral guidewire 48 may be slideably disposed throughout the contralateral delivery catheter 130, such that the guidewire can be pushed distally relative to the contralateral delivery catheter. In one embodiment by advancing the contralateral guidewire 48 cephalad the contralateral end cap 140 is translated distally to expose the distal end of the contralateral attachment system 80. Once the contralateral attachment system 80 is exposed the contralateral release wire 136 is withdrawn proximally undoing the fastening which prevents expansion of the system. The self-expanding contralateral attachment system 80 is then free to expand due to spring forces. The contralateral attachment system 80 then forces the contralateral inferior member 46 of the bifurcated graft 24 into the wall of the contralateral iliac artery 204. The spring forces will be sufficient to maintain the contralateral inferior member open and secure in the artery.

Once the contralateral release wire 136 is withdrawn from the contralateral inferior member 46, and the contralateral attachment system 80, the contralateral delivery catheter 130 is freed from the remainder of the grafting system 20. As the attachment system expands, the contralateral delivery catheter is separated from the proximal end of the contralateral attachment system. Therefore, the elongated hollow member 144 and contralateral guidewire 48, along with the contralateral end

cap 140, are free to be removed from the patient's vasculature. By pulling the elongated hollow member and guidewire proximally, the physician removes these components through the contralateral iliac and femoral arteries.

Either before or after the positioning and securing of the contralateral inferior member 46, the ipsilateral inferior member 32 may be positioned and secured. The ipsilateral inferior member may be positioned in the ipsilateral iliac artery 200 by pulling the ipsilateral delivery catheter 36, or the main delivery catheter 23 and ipsilateral delivery catheter together proximally. Once the ipsilateral inferior member is in place, the ipsilateral attachment system 78 may be deployed.

The ipsilateral attachment system 78 is deployed first by retracting the ipsilateral delivery catheter 36 to expose the ipsilateral attachment system and then pulling the ipsilateral release wire 112 proximally. In the preferred embodiment this is accomplished by the physician pulling the ipsilateral pull ring 110 on the control assembly 54. The ipsilateral pull ring is attached to the ipsilateral release wire which is slidably disposed throughout the grafting system 20 and fastened into the ipsilateral inferior member 46 and the ipsilateral attachment system 78. Pulling the release wire proximally will unfasten the ipsilateral attachment system allowing it to expand under its own spring force. The attachment system will expand the ipsilateral inferior member 32 and secure it to the wall of the ipsilateral iliac artery 200. The ipsilateral release wire may then be entirely removed from grafting system.

Once the superior attachment system 60, the ipsilateral attachment system 78 and contralateral attachment system 80, have been anchored, the remainder of the grafting system 20, may be removed from the patient's vasculature. This will leave only the bifurcated graft 24, and the attachment systems in position and secured across the aortic bifurcation. The grafting system, now free from the bifurcated graft and the contralateral delivery system components is withdrawn through the ipsilateral iliac and femoral arteries. Prior to withdrawal the ipsilateral delivery catheter 36 may be withdrawn into the main delivery catheter 23, and the balloon catheter assembly 26 withdrawn so that only the expandable balloon member 30 extends distally from the main catheter. This will prevent snagging the components in the patient's vasculature.

The entire procedure described herein can be observed under fluoroscopy. The relative positioning of the bifurcated graft 24 and the expandable balloon member 30 can be readily ascertained by the radiopaque markers 116 provided on the graft, and the radiopaque marker on the balloon catheter shaft 28 or the radiopaque inferior attachment systems themselves. If any twisting of the graft has occurred between placement of the superior attachment system 60 and the inferior attachment systems then the twisting can be readily ascertained by observing the series of markers. Adjustments to eliminate any twisting which may have occurred can be made before exposing the attachment systems by rotation of the balloon catheter assembly 26. Any excessive graft compression may also be ascertained by observing the radiopaque markers under fluoroscopy.

Post implant fluoroscopy procedures may be utilized to confirm the proper implantation of the device by the use of a conventional pigtail catheter or by injecting dye into the guide wire lumen of the balloon catheter shaft. Thereafter the sheath can be removed from the femoral artery and the femoral artery closed with conventional suturing techniques. A blood tight seal at the three attachment sites establish a complete repair of the vessel. Thereafter, tissues may begin to grow into the graft within two to four weeks with tissue completely covering the interior side of the graft within six months so that no portion of the graft thereafter would be in communication with the blood circulating in the vessel. Moreover, blood-tight seals are provided at the three attachment sites by the cooperation of the attachment systems and the graft to thereby accomplish a complete repair.

While several particular forms of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. For example, references to materials of construction and certain dimensions are also not intended to be limiting in any manner and other materials and dimensions could be substituted and remain within the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED IS:

1. A system for intraluminally delivering a bifurcated graft across a corporeal lumen, the corporeal lumen being formed of a superior vessel having a vessel bifurcation and extending into an ipsilateral vessel and a contralateral vessel, the system comprising:

a bifurcated graft formed of a superior member having a graft bifurcation and extending into an ipsilateral member and a contralateral member;

a set of positioning mechanisms capable of intraluminally positioning the bifurcated graft into the corporeal lumen;

a set of attaching mechanisms capable of attaching the superior member to the superior vessel, the ipsilateral member to the ipsilateral vessel, and the contralateral member to the contralateral vessel;

a main catheter housing the bifurcated graft, the set of positioning mechanisms, and the set of attaching mechanisms, the main catheter configured as a hollow cylindrical tube defining an inner diameter measuring less than seven millimeters;

whereby the bifurcated graft, the set of positioning mechanisms and the set of attaching mechanisms are housed within the main catheter for intraluminal delivery of the bifurcated graft.

2. The system of claim 1, wherein the set of attaching mechanisms includes an expandable anchor attached to the superior member of the bifurcated graft.

3. The system of the claim 2 wherein the expandable anchor is self expanding, and the set of attaching mechanisms further includes a release wire which releasably constricts the expandable anchor in an unexpanded condition.

4. The system of claim 2, wherein the set of attaching mechanisms further includes a balloon catheter capable of expanding the expandable anchor.

5. The system of claim 2, wherein the expandable anchor includes vessel engaging members.

6. The system of claim 1, wherein the set of attaching mechanisms includes a first expandable anchor attached to the superior member of the bifurcated graft and a second expandable anchor attached to the ipsilateral member of the bifurcated graft.

7. The system of claim 6 wherein the set of attaching mechanisms further includes a hollow cylinder extending throughout the main catheter and removably positioned within the ipsilateral member of the bifurcated graft.

8. The system of claim 7 wherein the set of attaching mechanisms further includes a release wire extending throughout the hollow cylinder and releasably attaching the hollow cylinder to the ipsilateral member of the bifurcated graft and the second expandable anchor.

9. The system of claim 8 wherein the expandable anchor is self-expanding and the release wire releasably constricts the second expandable anchor in an unexpanded condition.

10. The system of claim 6 wherein the second expandable anchor has a distal end

and the set of positioning mechanisms further includes a first end cap disposed about the distal end of the second expandable anchor while the second expandable anchor is in an unexpanded condition.

11. The system of claim 1 wherein the set of attaching mechanisms includes a first expandable anchor attached to the superior member of the bifurcated graft, a second expandable anchor attached to the ipsilateral member of the bifurcated graft and a third expandable anchor attached to the contralateral member of the bifurcated graft.

12. The system of claim 1, wherein the set of positioning mechanisms includes a main guidewire.

13. The system of claim 1 wherein the set of positioning mechanisms includes a contralateral guidewire removably attached to the contralateral member of the bifurcated graft.

14. The system of claim 13 wherein the contralateral guidewire has a proximal end and a bulbous portion attached to said proximal end.

15. The system of claim 13 wherein the contralateral guidewire is configured as a stiffened rod.

16. The system of claim 13 wherein the contralateral guidewire is configured as a coiled wire.

17. The system of claim 11 wherein the second expandable anchor has a distal end,

and the third expandable anchor has a distal end, and the set of positioning mechanisms further includes a first end cap disposed about the distal end of the second expandable anchor while the second expandable anchor is in an unexpanded

condition, and a second end cap disposed about the distal end of the third expandable anchor while the third expandable anchor is in an unexpanded condition.

18. The system of claim 1 wherein the set of positioning mechanisms includes a secondary catheter encompassing at least a portion of the ipsilateral member of the bifurcated graft.

19. The system of claim 1 wherein the set of positioning mechanisms includes a secondary catheter encompassing at least a portion of the contralateral member of the bifurcated graft.

20. The system of claim 19 wherein the secondary catheter is folded within the main catheter for intraluminal delivery.

21. The system of claim 19 wherein the set of attachment mechanisms includes an expandable anchor attached to the contralateral member of the bifurcated graft and at least partially encompassed by the secondary catheter.

22. The system of claim 21 wherein the set of attachment mechanisms further includes a hollow cylinder extending throughout the secondary catheter and removably positioned within the contralateral member of the bifurcated graft.

23. The system of claim 22 wherein the expandable anchor is self-expanding and the release wire releasably constricts the expandable anchor in an unexpanded condition.

24. The system of claim 1 further comprising:

a hollow metal cylinder attached within the main catheter and encompassing at least a portion of the bifurcated graft.

25. A system for placing a bifurcated graft in a lumen formed by a wall proximate a vascular bifurcation having an aneurysm, the system comprising:

a bifurcated graft having a superior extremity, an ipsilateral inferior extremity, and a contralateral inferior extremity;

a first anchoring mechanism attached to the superior extremity;

a second anchoring mechanism attached to the ipsilateral inferior extremity and configured to be self-expandable;

a third anchoring mechanism attached to the contralateral inferior extremity and configured to be self-expandable;

a first release wire releasably attached to the second anchoring mechanism such that the second anchoring mechanism maintains an unexpanded condition;

a second release wire releasably attached to the third anchoring mechanism such that the third anchoring mechanism maintains an unexpanded condition; and

a delivery catheter configured to contain the bifurcated graft, the first anchoring mechanism, the second anchoring mechanism, the third anchoring mechanism, the first release wire and the second release wire.

26. The system of claim 25, wherein the first anchoring mechanism is configured to be self-expanding, and the system further includes a third release wire releasably attached to the first anchoring mechanism such that the first anchoring mechanism maintains an unexpanded condition.

27. The system of claim 25, wherein the first anchoring mechanism includes a plurality of wall-engaging members.

28. The system of claim 25, further comprising:

a balloon catheter configured to expand the first anchoring mechanism into an expanded state.

29. The system of claim 25, further comprising:

a delivery catheter configured to encompass said system for intraluminal delivery.

30. The system of claim 29, wherein the delivery catheter has a generally tubular shape defining an interior diameter of less than 7 millimeters and greater than 6 millimeters.

31. The system of claim 25, further comprising:

a secondary catheter which encompasses at least a portion of the second anchoring mechanism.

32. The system of claim 31, further comprising:

a cylinder slideably disposed throughout the secondary catheter and encompassing the first release wire.

33. The system of claim 25, further comprising a secondary catheter which encompasses at least a portion of the third anchoring system.

34. The system of claim 33, wherein the secondary catheter is folded for intraluminal delivery.

35. The system of claim 33, further comprising a cylinder slideably disposed throughout the secondary catheter and encompassing the second release wire.

36. The system of claim 33, further comprising:

a guidewire disposed throughout the secondary catheter.

37. A method of positioning a bifurcated graft across a vascular bifurcation formed by an upstream vessel a first down stream vessel and a second downstream vessel using a bifurcated graft delivery system having a first catheter, a bifurcated graft formed by an upstream duct, a first downstream duct and a second downstream duct, disposed within the first catheter, a second catheter connected to the first downstream duct and disposed within the first catheter, and a third catheter connected to the second downstream duct and folded within the first catheter, and a snare guidewire comprising the steps of:

advancing the delivery system through the first downstream vessel and into the upstream vessel;

withdrawing the first catheter such that the bifurcated graft, the second catheter and the third catheter are exposed within the upstream vessel;

unfolding the third catheter;

advancing the snare guidewire through the second downstream vessel;

snaring the third catheter with the snare catheter;

pulling the first downstream duct into the first downstream vessel by withdrawing the second catheter; and

pulling the second downstream duct into the second downstream vessel by withdrawing the third catheter.

38. A method for repairing a bifurcated vascular vessel formed by an upstream vessel a first downstream vessel and a second downstream vessel using a bifurcated graft delivery system having a delivery catheter, a bifurcated graft formed by an upstream duct, a first downstream duct and a second downstream duct, disposed within the delivery catheter, a first expandable anchoring mechanism attached to the first downstream duct, said first expandable anchoring mechanism being self-expanding, a first release wire releasably fastened to the first expandable anchoring mechanism such that the first expandable anchoring mechanism is maintained in an unexpanded state, a second expandable anchoring mechanism attached to the second downstream duct, said second expandable anchoring mechanism being self-expanding, a second release wire releasably fastened to the second expandable anchoring mechanism such that the second expandable anchoring mechanism is maintained in an unexpanded state, and a third expandable anchoring mechanism attached to the upstream duct, comprising the steps of:

inserting the bifurcated graft delivery system intraluminally into the bifurcated vascular vessel;

withdrawing the delivery catheter such that the bifurcated graft is exposed within the bifurcated vascular vessel;

positioning the bifurcated graft within the bifurcated vascular vessel, such that the upstream duct extends into the upstream vessel, the first

downstream duct extends into the first downstream vessel, and the second downstream duct extends into the second downstream vessel;

anchoring the first downstream duct to the first downstream vessel by releasing the first release wire from the first downstream expandable anchoring mechanism whereby the first expandable downstream mechanism expands into the first downstream vessel;

anchoring the second downstream duct to the second downstream vessel by releasing the second release wire from the second downstream expandable anchoring mechanism whereby the second expandable downstream mechanism expands into the second downstream vessel;

anchoring the upstream duct to the upstream vessel by expanding the third expandable anchoring mechanism into the upstream vessel.

39. The method of claim 38, wherein

the third expandable anchoring mechanism is self-expanding;

the bifurcated graft delivery system further includes a third release wire releasably fastened to the third expandable anchoring mechanism such that the third expandable anchoring mechanism is maintained in an unexpanded state; and

the anchoring the upstream duct step includes releasing the third pullwire from the third downstream expandable mechanism whereby the third expandable anchoring mechanism expands into the upstream vessel.

40. The method of claim 38, wherein the bifurcated graft delivery system includes a balloon catheter; and

the anchoring the upstream duct to the upstream vessel step includes inflating the balloon catheter such that the third expandable mechanism is expanded into the upstream vessel.

ABSTRACT

A reduced diameter intraluminal grafting system capable of deploying a bifurcated graft into a bifurcated vessel is described. The bifurcated graft is comprised of a main tubular member and two tubular legs with attachment systems configured into each of the three ends of the graft. The bifurcated graft along with the mechanisms required to position and attach the bifurcated graft fit within a single delivery catheter for intraluminal delivery. The bifurcated graft, positioning mechanisms and attaching mechanisms are configured such that a small diameter delivery catheter can be utilized. The methods of positioning and attaching the bifurcated graft are also described.

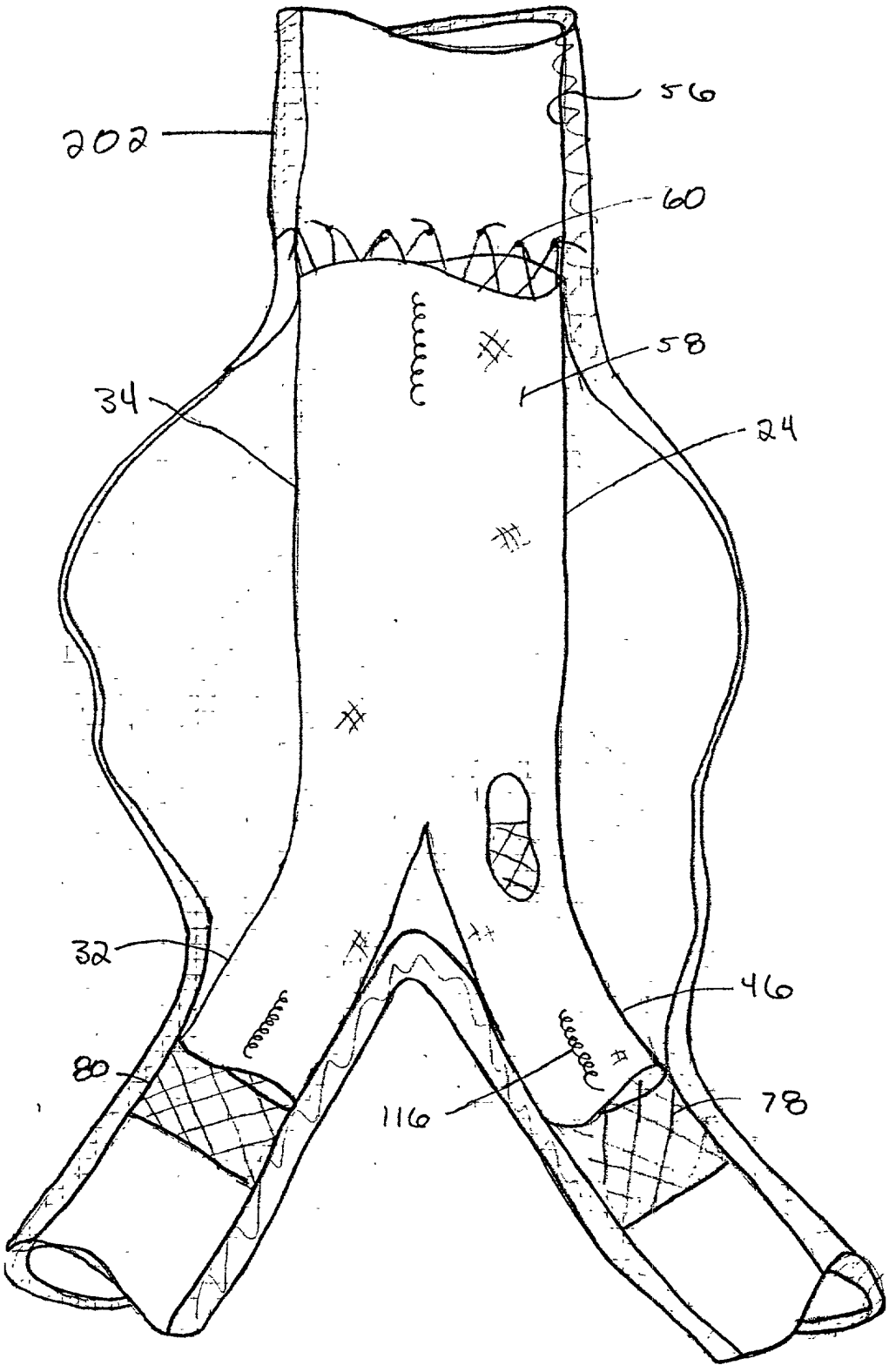

FIG. 1

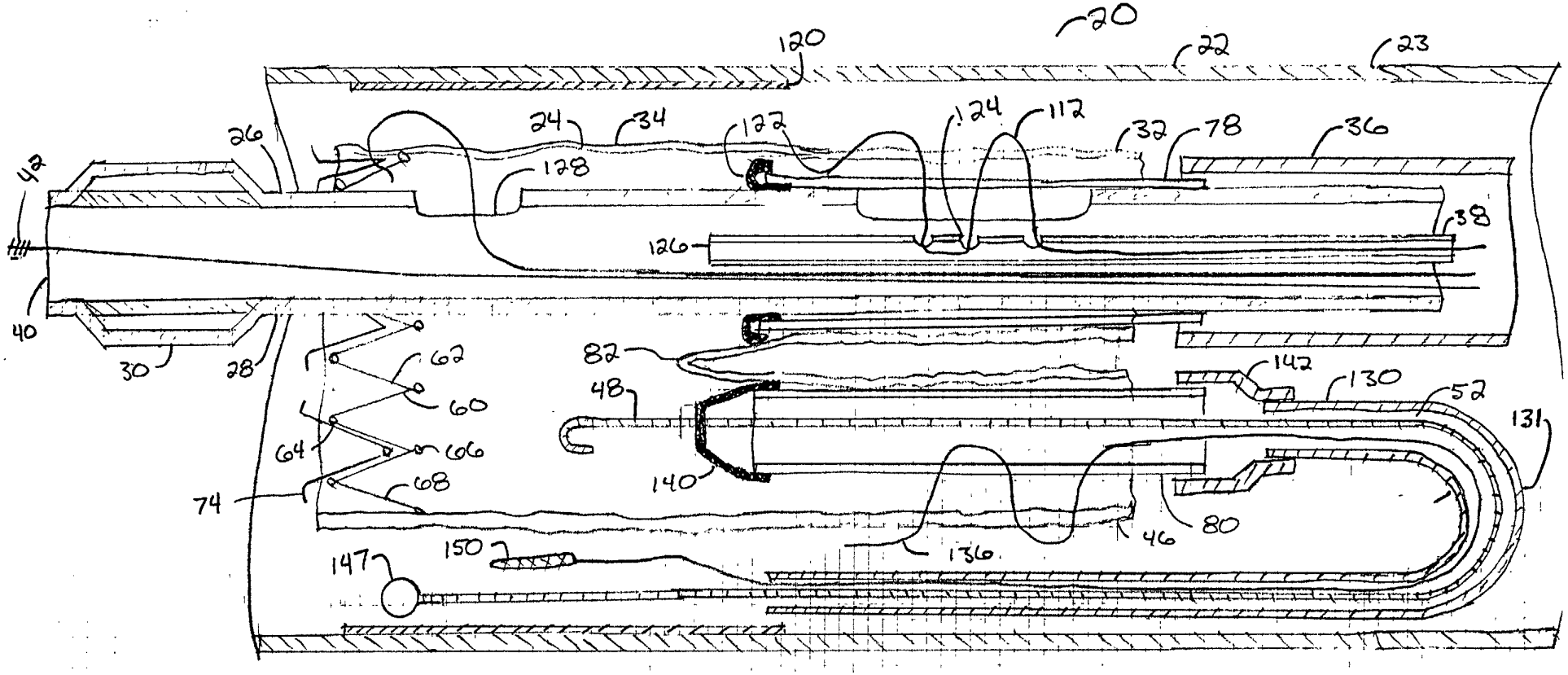
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FIG. 2

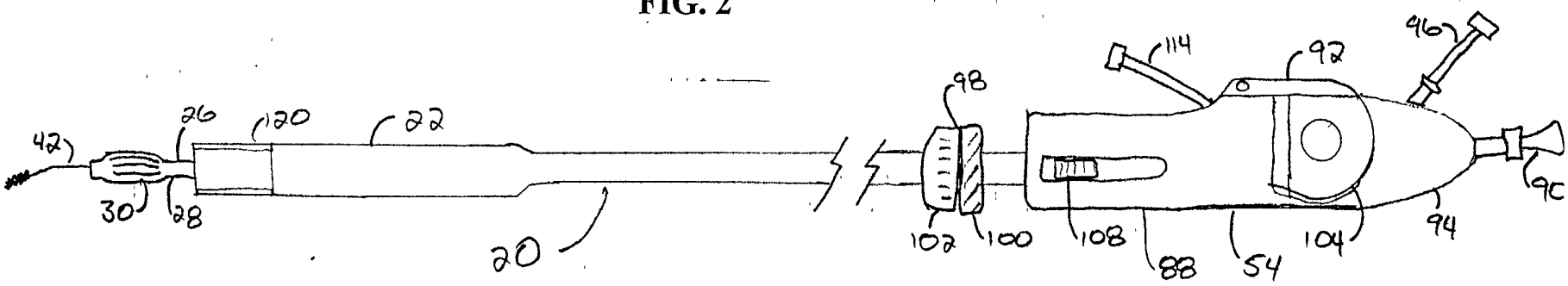
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FIG. 3

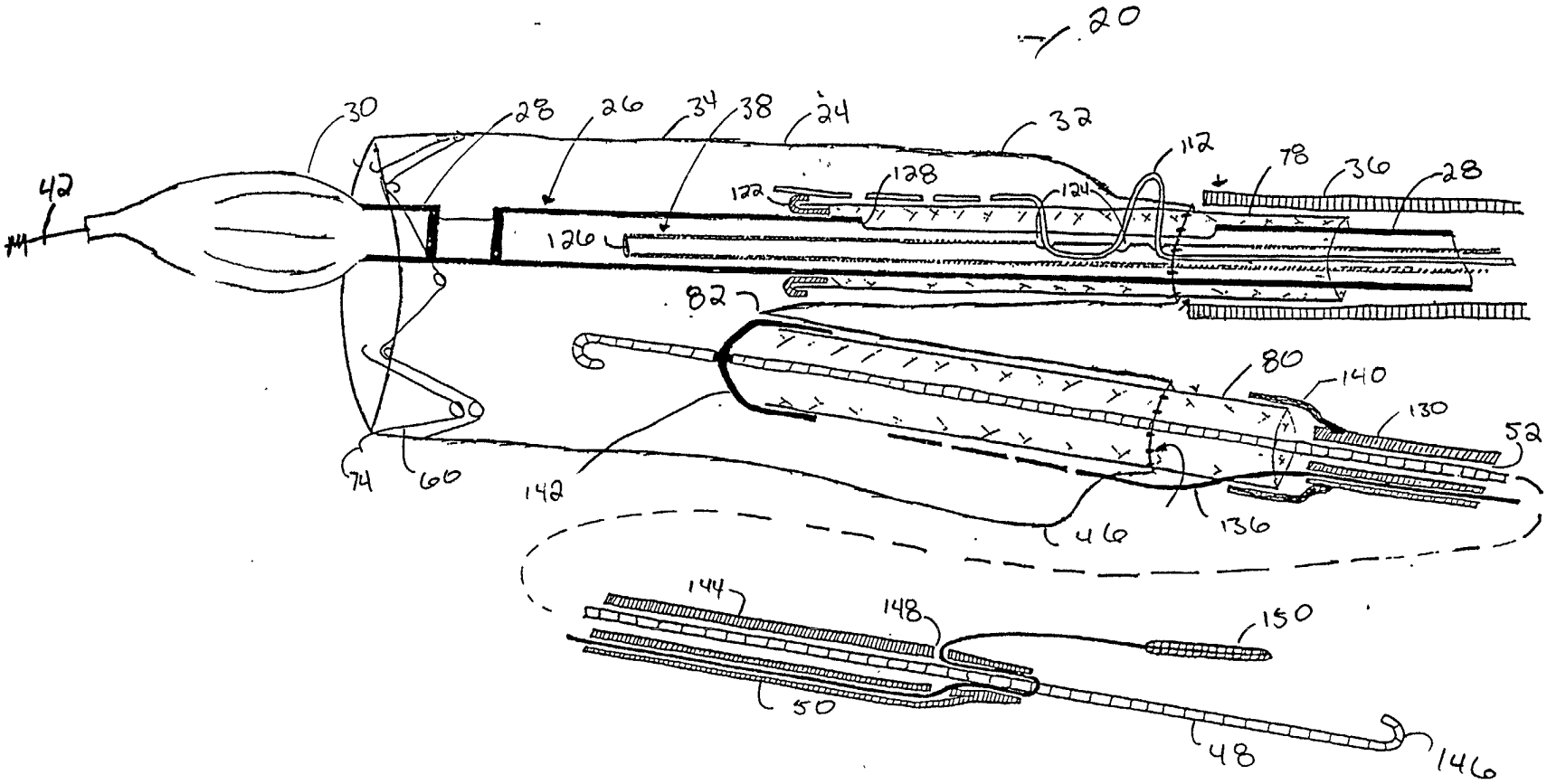

FIG. 4

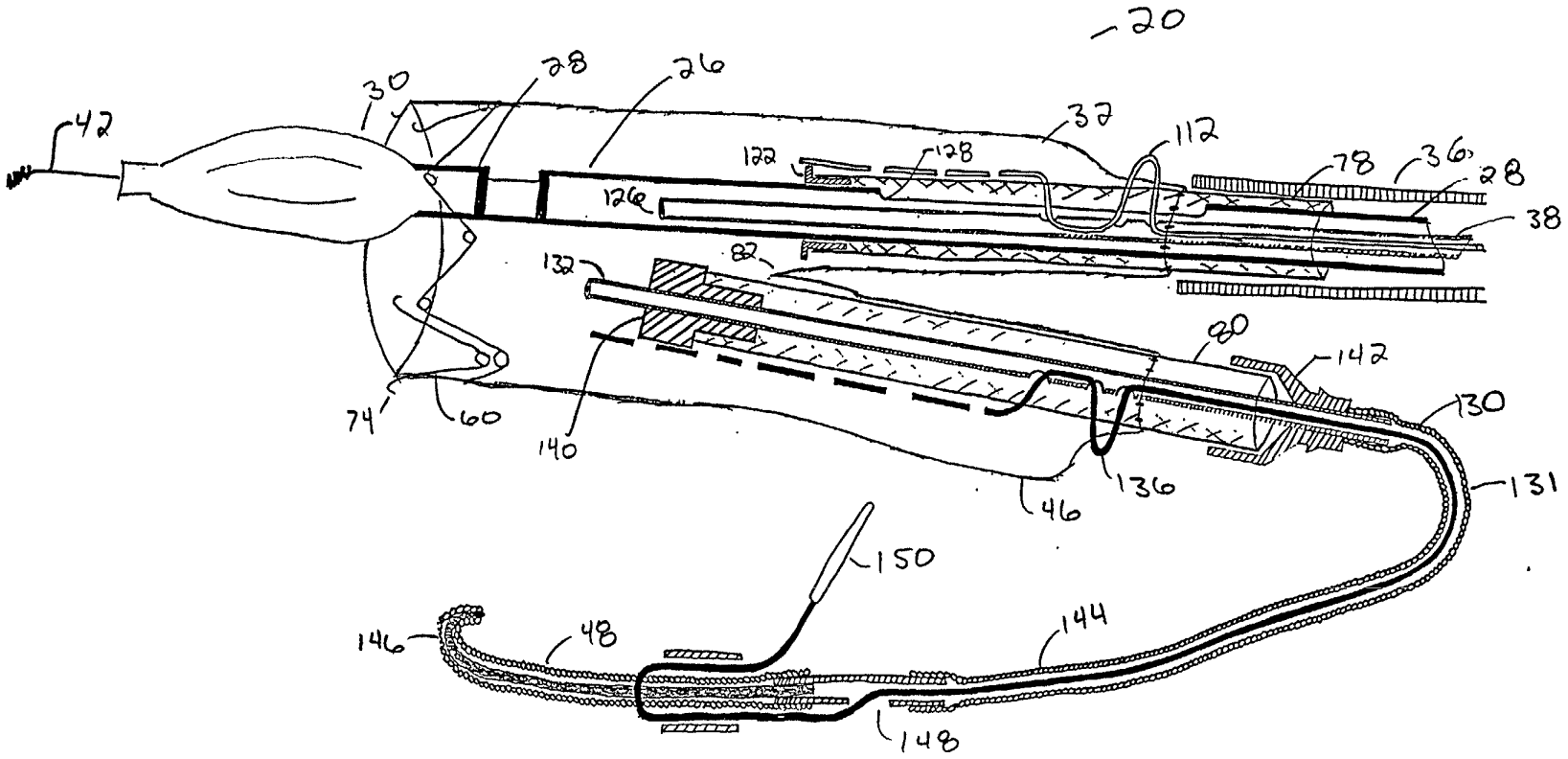
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FIG. 5

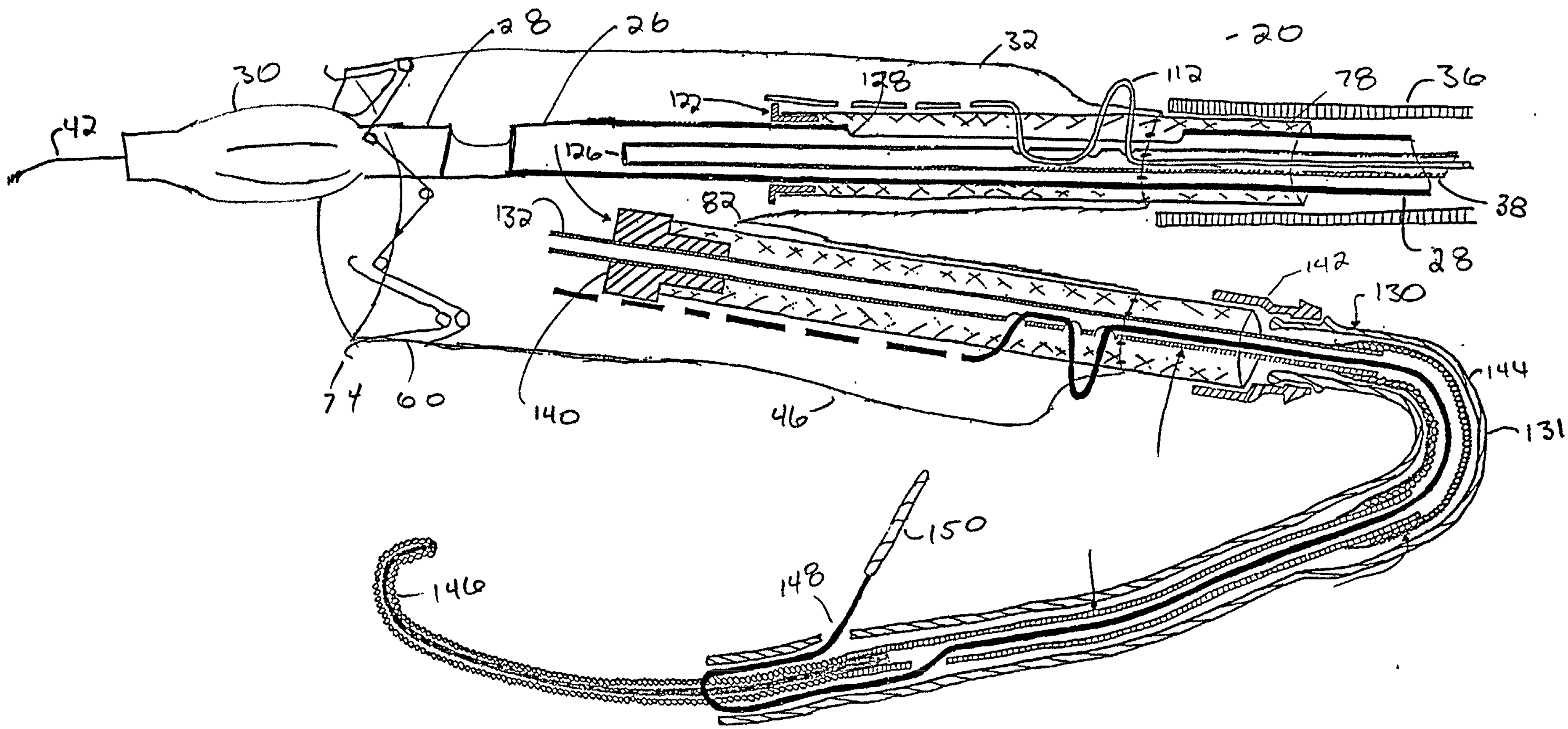
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FIG. 6

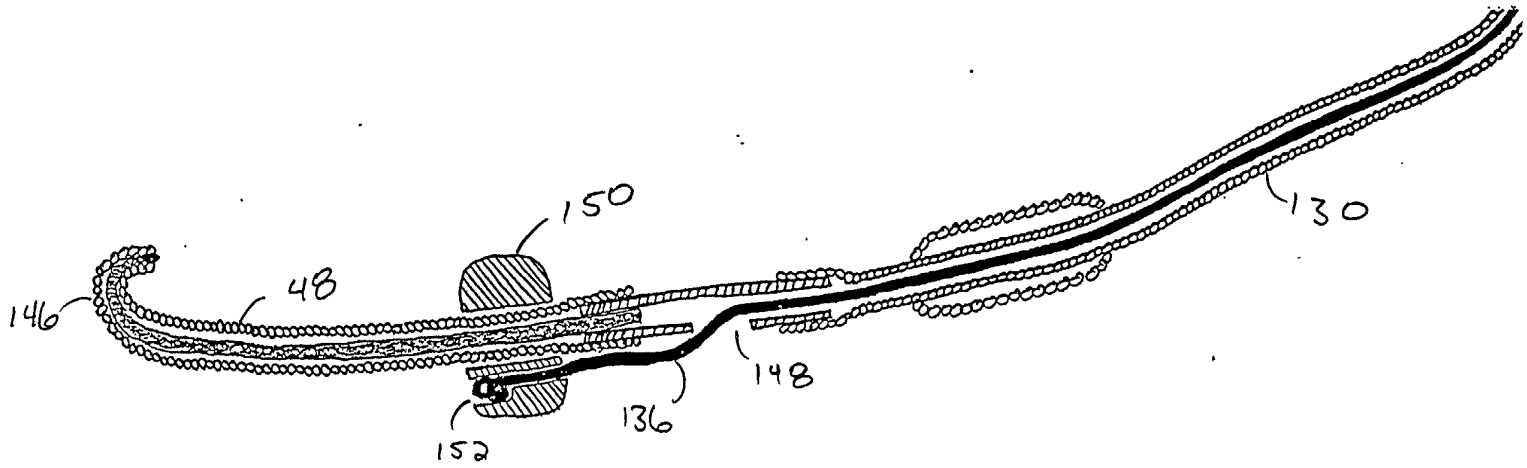


FIG. 7

FIG. 8

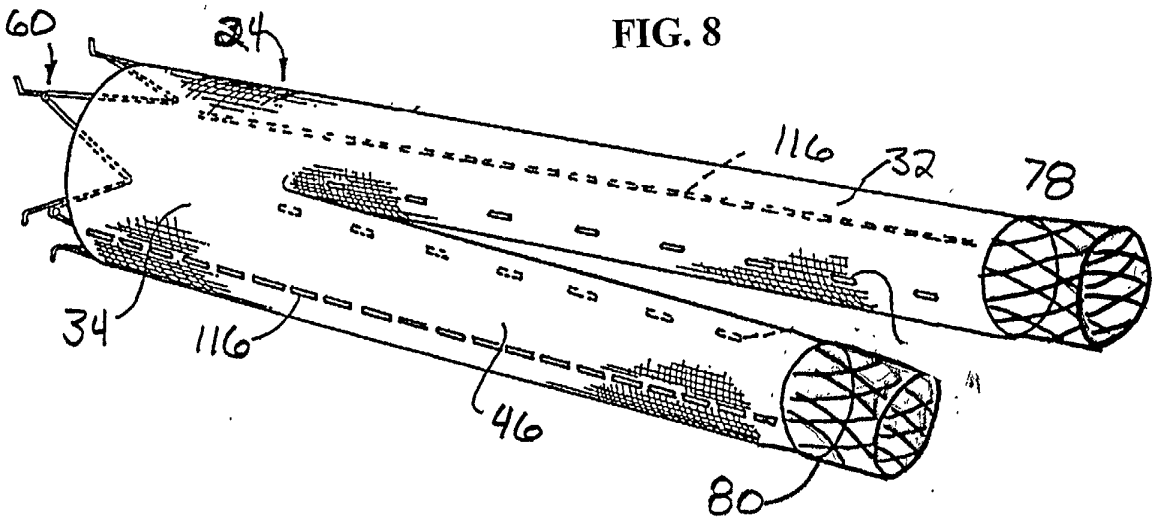


FIG. 10

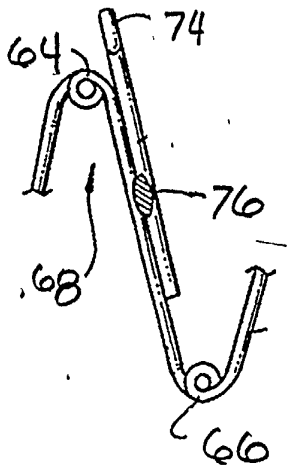


FIG. 9A

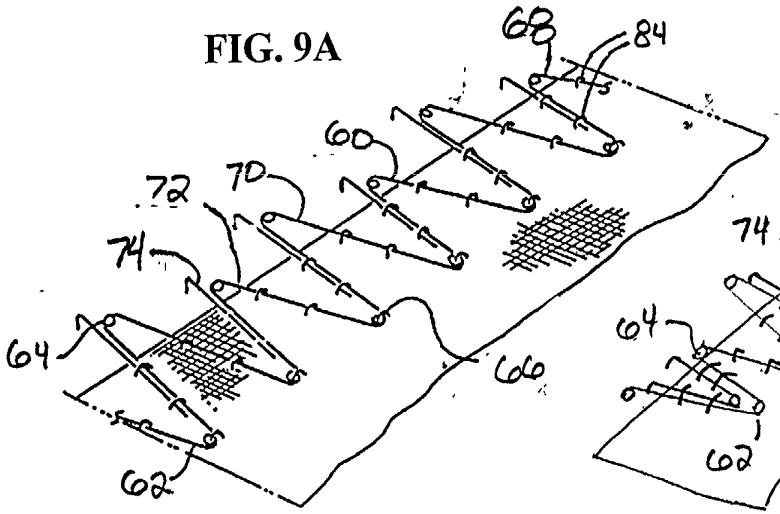


FIG. 9B

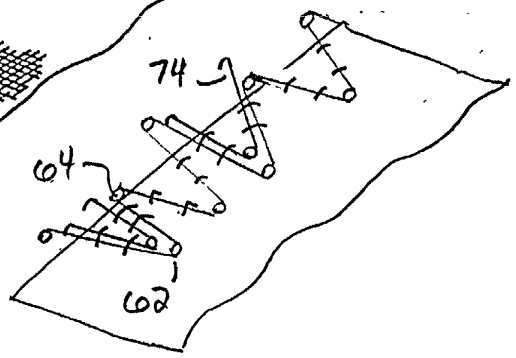
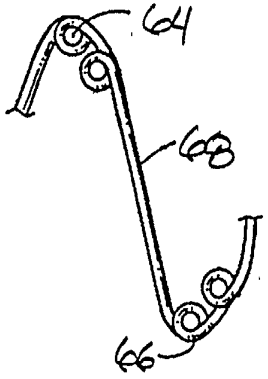


FIG. 11



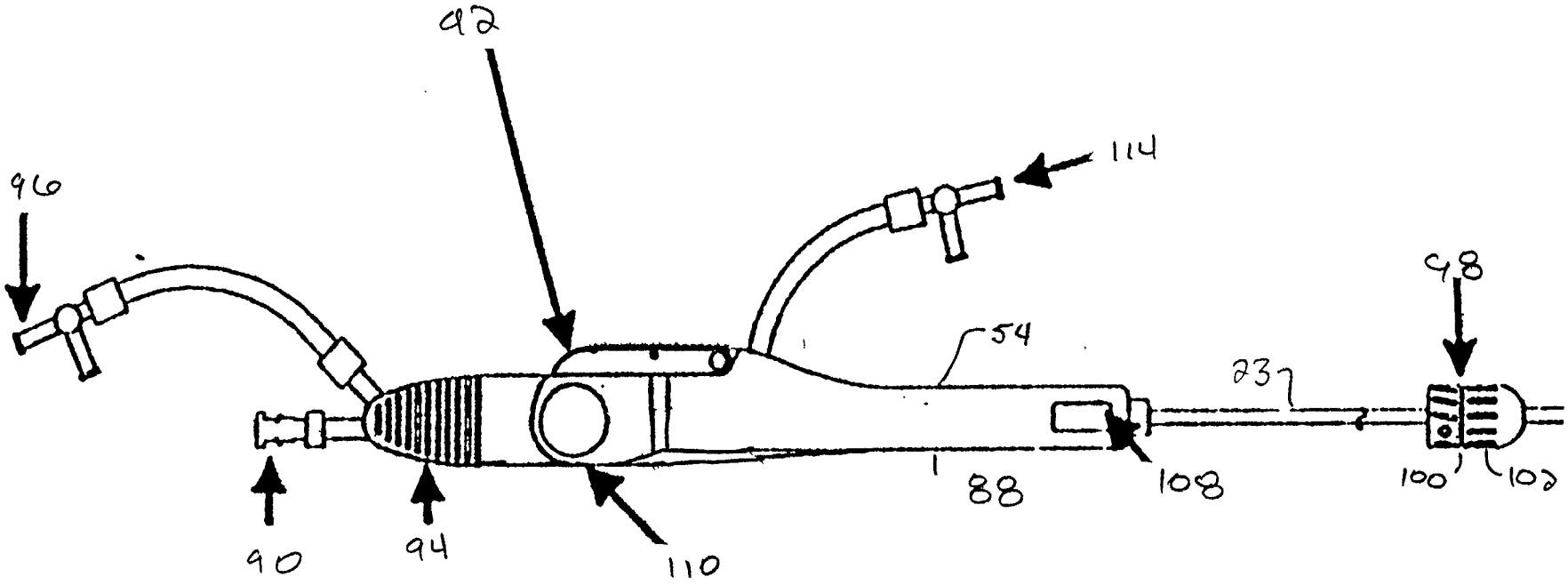


FIG. 12

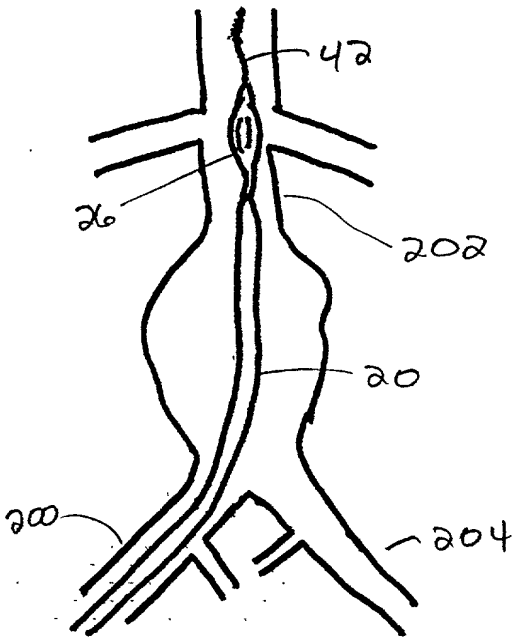


FIG. 13

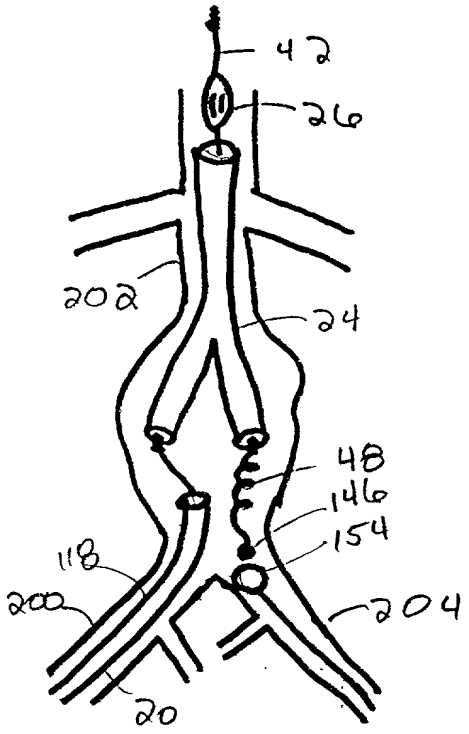


FIG. 14

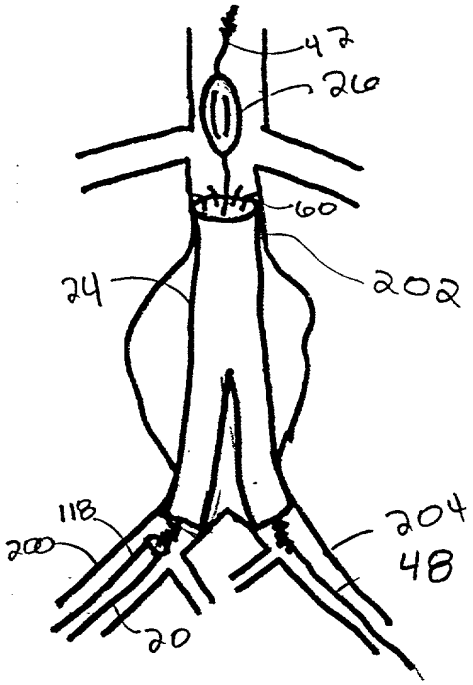


FIG. 15

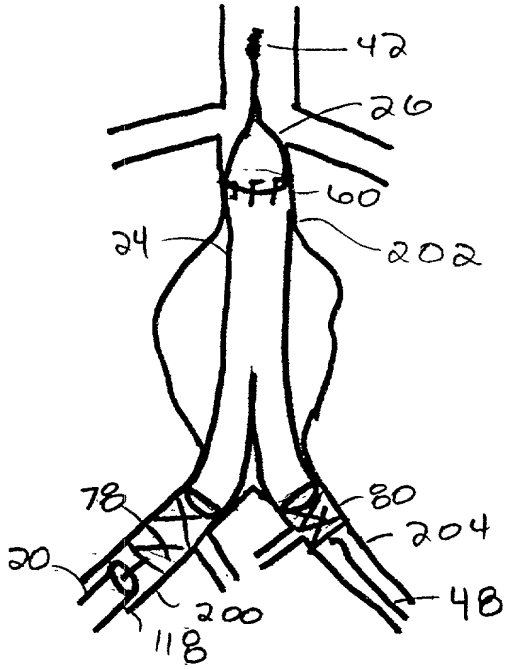


FIG. 16

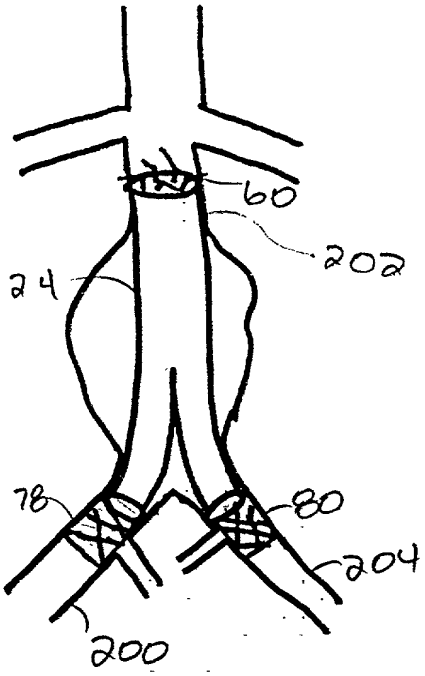


FIG. 17

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As the below named inventors, we hereby declare that:

Our residences, post office addresses and citizenships are as stated below next to our names,

We believe we are original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled REDUCED PROFILE GRAFTING SYSTEM the specification of which (check one)

_X_ is attached hereto
____ was filed on _____
Application Serial No. _____
and was amended on (or amended through) _____
(if applicable)

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above.

We acknowledge the duty to disclose information which is material patentability as defined in with Title 37, Code of Federal Regulations, Sec. 1.56.

We hereby claim foreign priority benefits under Title 35, United States Code, Sec. 119 (a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
NONE				
Number	Country	Day/Month/Year filed	Yes	No

We hereby claim the benefit under Title 35, United States Code, Sec. 119(e) of any United States provisional application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Sec. 112, we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Sec. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

NONE		
Appln. Serial No.	Filing Date	Status (patented, pending abandoned)

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

We hereby appoint the following attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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Inventor's signature: Reid Hayashi

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Citizenship: USA

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